



PCT/GB 2004 / 0 0 2 6 8 8



INVESTOR IN PEOPLE

**PRIORITY
DOCUMENT**
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)

REC'D 12 AUG 2004

WIPO

PCT

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed

William Morell

Dated

3 August 2004

THE PATENT OFFICE

25JUN03 E817459-3 D02902

P01/7700 0.00-0314689.1

The Patent Office

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

24 JUN 2003

NEWPORT

Cardiff Road
Newport
Gwent NP9 1RH

1. Your reference

P3202-GB

2. Patent application number

(The Patent Office will fill in this part)

0314689.1

24 JUN 2003

3. Full name, address and postcode of the or of each applicant (underline all surnames)

LAMBERT, Anthony
8 Russell Avenue
Hartley
Plymouth
PL5 3RA

Patents ADP number (*if you know it*)

If the applicant is a corporate body, give the country/state of its incorporation

8461071001

4. Title of the invention

SUBCUTANEOUS TUNNELLER

5. Name of your agent (*if you have one*)

SHELLEY, Mark Raymond
7 Gay Street
Bath
BA1 2PH

"Address for service" in the United Kingdom to which all correspondence should be sent (*including the postcode*)

Patents ADP number (*if you know it*)

8305989001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (*if you know it*) the or each application number

Country

Priority application number
(*if you know it*)

Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (*Answer 'Yes' if:*

No

- a) any applicant named in part 3 is not an inventor, or
 - b) there is an inventor who is not named as an applicant, or
 - c) any named applicant is a corporate body.
- See note (d))

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description 5 /

Claim(s) 2 /

Abstract

Drawing(s) 6 + 6

June

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translation of priority documents

Statement of inventorship and right to grant of a patent (*Patents Form 7/77*)

Request for preliminary examination and search (*Patents Form 9/77*)

Request for substantive examination (*Patents Form 10/77*)

Any other documents
(please specify)

11. I/We request the grant of a patent on the basis of this application.

Signature



Date

24 June 2003

12. Name and daytime telephone number of person to contact in the United Kingdom
SHELLEY, Mark Raymond

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

- If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.
- Write your answers in capital letters using black ink or you may type them.
- If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- If you have answered 'Yes' Patents Form 7/77 will need to be filed.
- Once you have filled in the form you must remember to sign and date it.
- For details of the fee and ways to pay please contact the Patent Office.

DUPLICATE

1

SUBCUTANEOUS TUNNELLER

This invention relates to subcutaneous surgical tunnellers and in particular concerns a
5 tunneller suitable for use in orchidopexy surgery to correct undescended testis in the
human male body.

Cryptorchism (undescended testis) is a congenital condition where one or more testis
fail to descend from the abdominal cavity into the scrotal sac. If left untreated this
10 condition can result in an increased risk of testicular cancer. The condition is
corrected using orchidopexy surgery often using standard operating laparoscope
surgical instruments, first to dissect and immobilise the undescended testis with
respect to the abdominal wall and then to grasp the testis and apply caudal traction to
aid in dissection and move the testis into the scrotum so that it may be anchored in a
15 subcutaneous scrotal pouch (dartos pouch). This procedure can involve a minimum of
invasive surgery.

There is a requirement to simplify current surgical procedures so that trauma of the
surrounding tissue is minimised and also to provide a quicker and more reliable
20 procedure using the minimum of invasive instruments.

According to an aspect of the invention there is provided a one-piece orchidopexy
tunneller comprising an elongate body having a tunnelling head at one end thereof
and a testicle attachment means at the opposite end thereof for attachment to a testicle

to be repositioned in the human body by means of a surgical stitch during orchidopexy surgery.

The orchidopexy tunneller of the present invention readily enables orchidopexy surgery to be undertaken by creating an incision in the abdominal cavity in the region of the undescended testis, inserting the tunneller in the incision so formed and feeding the tunneller subcutaneously to the scrotum so that the tunneller head creates a dartos pouch for later anchoring the undescended testis within the scrotum. A further incision can then be made in the scrotum so that the tunneller head can be fed through the scrotum and out of the patient's body until the other end of the tunneller is positioned in the region of the first incision where the undescended testis is attached to that end of the tunneller so that further movement of the tunneller through the abdominal cavity and scrotum applies caudal traction so that the testis follows the end of the tunneller into the scrotum where the testis can be detached from the end of the tunneller and anchored in the scrotum with the procedure being completed by closing the abdominal and scrotum incisions. This is a particularly effective surgical procedure since the tunneller is moved in a single direction only entering the first incision in the abdominal cavity and exiting through the incision in the scrotum with the tunnel so formed allowing the testis to be repositioned. The tunneller of the present invention is particularly suitable for this surgical procedure since the tunnelling head is integrally formed at the end of the elongate body of the tunneller so that the tunnel can be formed by an appropriately sized tunneller head selected from a group of tunnellers having different size heads corresponding to different size testis thereby to correctly size the tunnel with respect to the testis to be moved therethrough.

Preferably the tunneller is capable of being secured to the testicle to be moved by means of a surgical stitch. It is sufficient to anchor the testis to the end of the tunneller opposite the tunneller head and this may conveniently be implemented during the surgical procedure by means of a stitch which engages a suitable feature on the end of the tunneller. The attachment means may comprise an aperture provided in the end of the body of the tunneller opposite the tunneller head. The aperture conveniently enables the stitch to be anchored to the end of the tunneller in a reliable manner.

10

Preferably the elongate body is arcuate so that the tunneller may be readily manipulated by the surgeon during the initial procedure of inserting the tunneller and forming the subcutaneous tunnel prior to attachment of the testis to the attachment means at the end of the body.

15

The invention also comprehends a uni-directional orchidopexy tunneller. In this respect it is to be understood that the term "uni-directional" refers to the one direction of movement of the tunneller within the patient's body. The invention also comprehends a kit of tunnellers having different size tunneller heads.

20

An embodiment of the present invention will now be more particularly described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a schematic view of an orchidopexy surgical tunneller according to

one arrangement of the present invention;

Figure 2 is a schematic representation of the different size tunneller heads corresponding to different size testis;

Figures 3-7 show various stages of an orchidopexy surgical procedure using a surgical tunneller instrument according to an arrangement of the present invention.

Referring to Figure 1 an orchidopexy tunneller 10 for use in orchidopexy surgery comprises elongate body 12 in the form of an arcuate rod. A tunneller head 14 is provided at one end of the elongate body 12 and a testis attachment means in the form of an aperture 16 is provided at the opposite end thereof. The tunneller head, elongate body and aperture 16 are integrally formed as a one-piece surgical instrument. The invention contemplates a set of tunnellers having different size heads so that a tunneller may be selected from a set of different size tunnellers each having a head 14 corresponding to a different size of testis (see Figure 2) so that an appropriate size tunneller may be used for the particular size of testis to be re-positioned. In the illustration of Figure 1 the end of the tunneller containing the aperture and encircled at 17 is shown in greater (enlarged) detail at 19.

The aperture 16 readily enables the testis to be moved by the tunneller to be attached to the end of the tunnel by means of a surgical stitch looped through the aperture 16. As can be seen in the drawing the aperture is formed in a tapered portion of the elongate body provided at the end of the body opposite the head 14.

The overall length dimension of the tunneller(s) of the illustrated embodiment present

invention is approximately 300mm. The tunneller(s) are preferable of a material suitable for surgical instruments, for example titanium or titanium alloy.

Referring now to Figures 3-7, in Figure 3 the first step in the orchidopexy procedure is shown where an incision 30 is made in the abdominal wall 32 in the region of the undescended testis with the testis 34 located externally of the patient's body. In the drawing of Figure 3 the tunneller body and tunneller head are shown on top of the patient's body lying in a position corresponding to the subcutaneous tunnel to be formed by the tunneller. The area 36 represents a surgical sheet covering the patient's body not involved in the surgical procedure. Figure 4 shows the tunneller inserted in the incision 30 with the tunneller head moved to a position within the scrotum 38 to form a subcutaneous scrotal pouch (dartos pouch) 40. In Figure 5 a second incision 42 is formed in the scrotum in the region of the tunneller head so that the tunneller may be pulled through the patient's body with the undescended testis 34 attached to the other end of the tunneller by means of a surgical stitch as shown in the drawings of Figures 6 and 7. The surgical procedure being completed by releasing the testis from the end of the tunneller and anchoring it to the scrotum prior to closing the incisions previously formed.

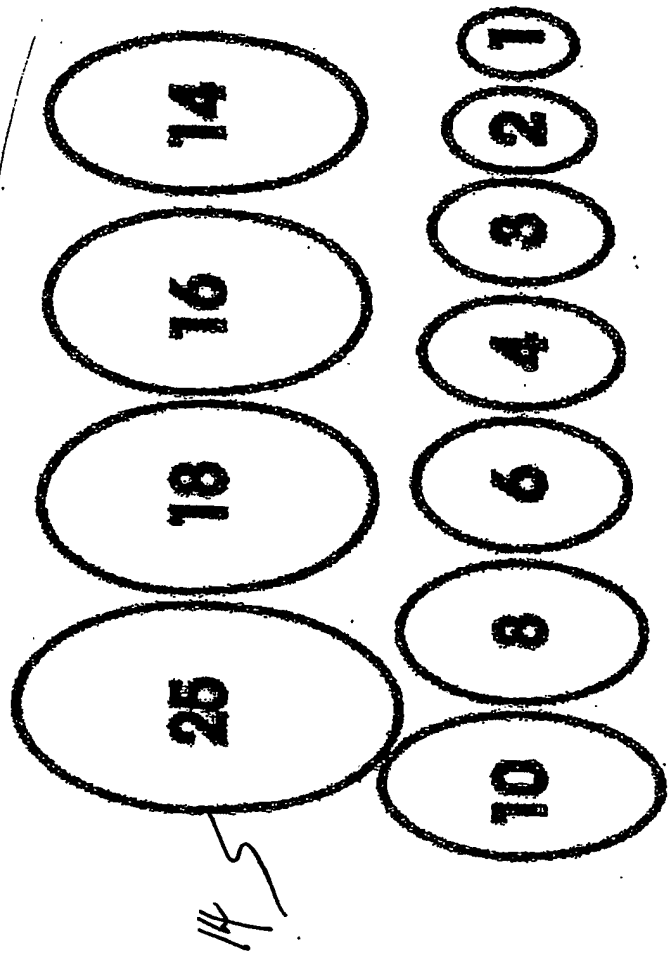
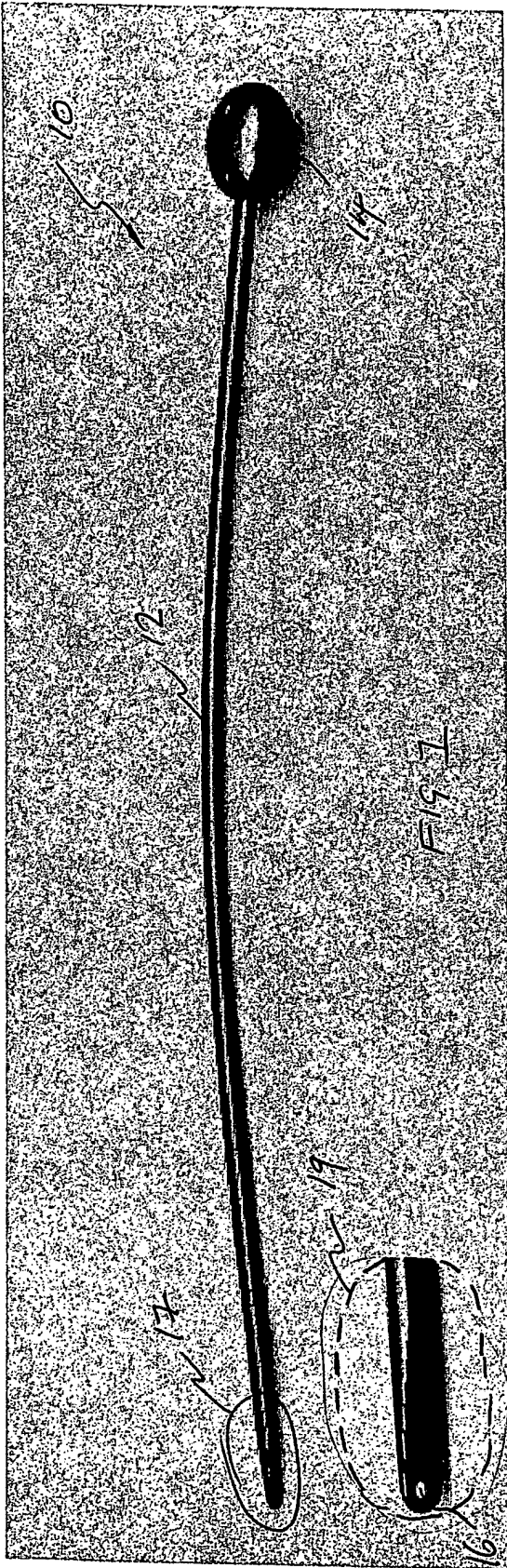
Although aspects of the invention have been described with reference to the embodiments shown in the accompanying drawings it is to be understood that the invention is not limited to these precise embodiments and that various changes and modifications may be effected without further inventive skill and effort.

CLAIMS

1. According to an aspect of the invention there is provided a one-piece
5 orchidopexy tunneller comprising an elongate body having a tunnelling head at one
head thereof and a testicle attachment means at the opposite end thereof for
attachment to a testicle to be repositioned in the human body by means of a surgical
stitch during orchidopexy surgery.
- 10 2. A tunneller as claimed in Claim 1 wherein the attachment means comprises an
aperture provided in the end of the body opposite the tunneller head.
3. A tunneller as claimed in Claim 1 and Claim 2 wherein the elongate body is
arcuate.
- 15 4. Is a tunneller as claimed in any preceding claim wherein the tunneller head is
of a shape and size representative of a human testis.
5. Is a tunneller as claimed in any preceding claim wherein the tunneller is of a
20 titanium or titanium alloy material.
6. Is a kit of orchidopexy tunnellers as claimed in any preceding claim wherein
the tunnelling head of each tunneller corresponds to a different size of testis.

7. A one-piece orchidopexy surgical tunneller.
8. An orchidopexy tunneller substantially as hereinbefore described and/or with reference to the accompanying drawings.

1/6



THIS PAGE BLANK '18PTO'

2/6

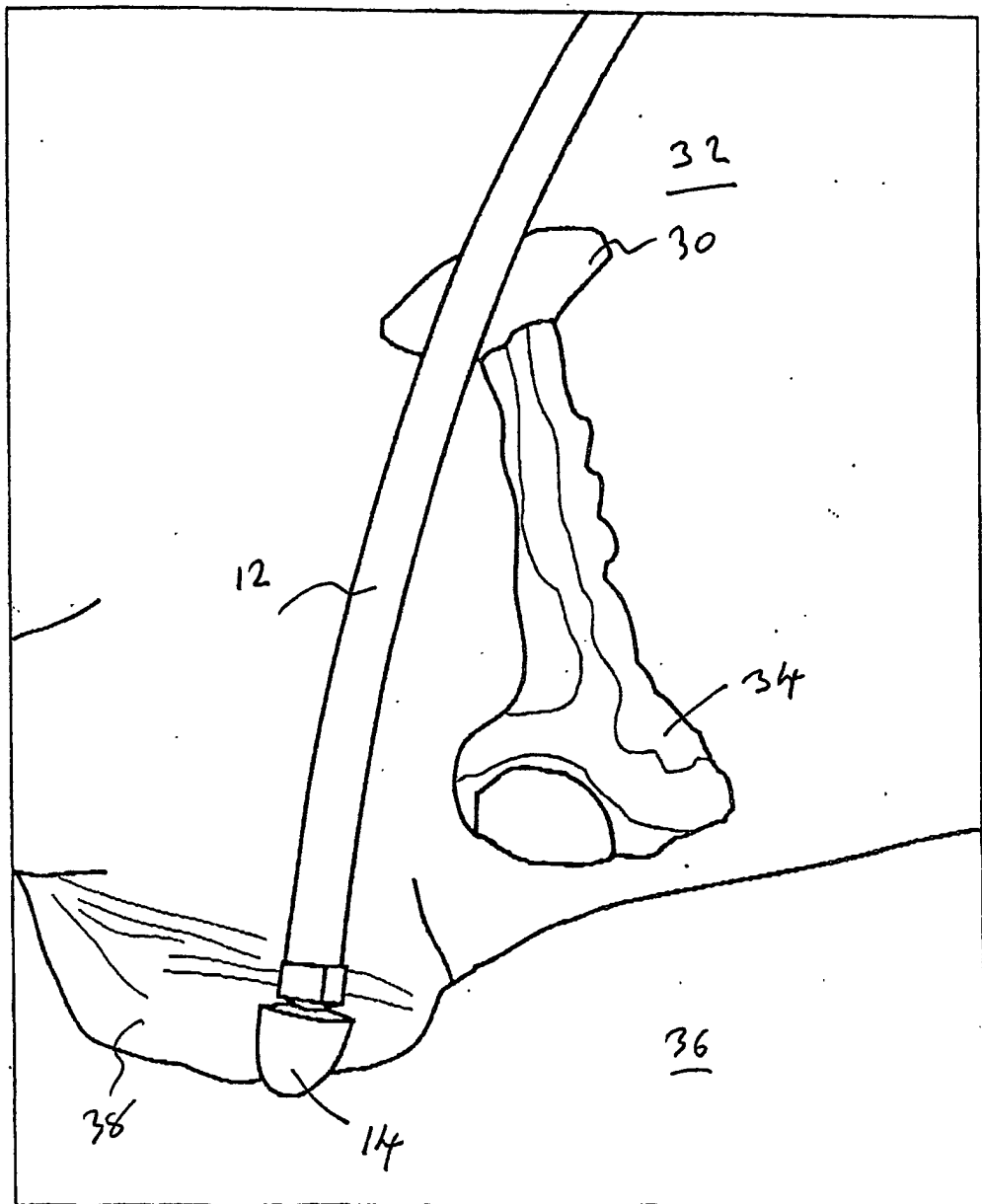


FIG 3

3/6

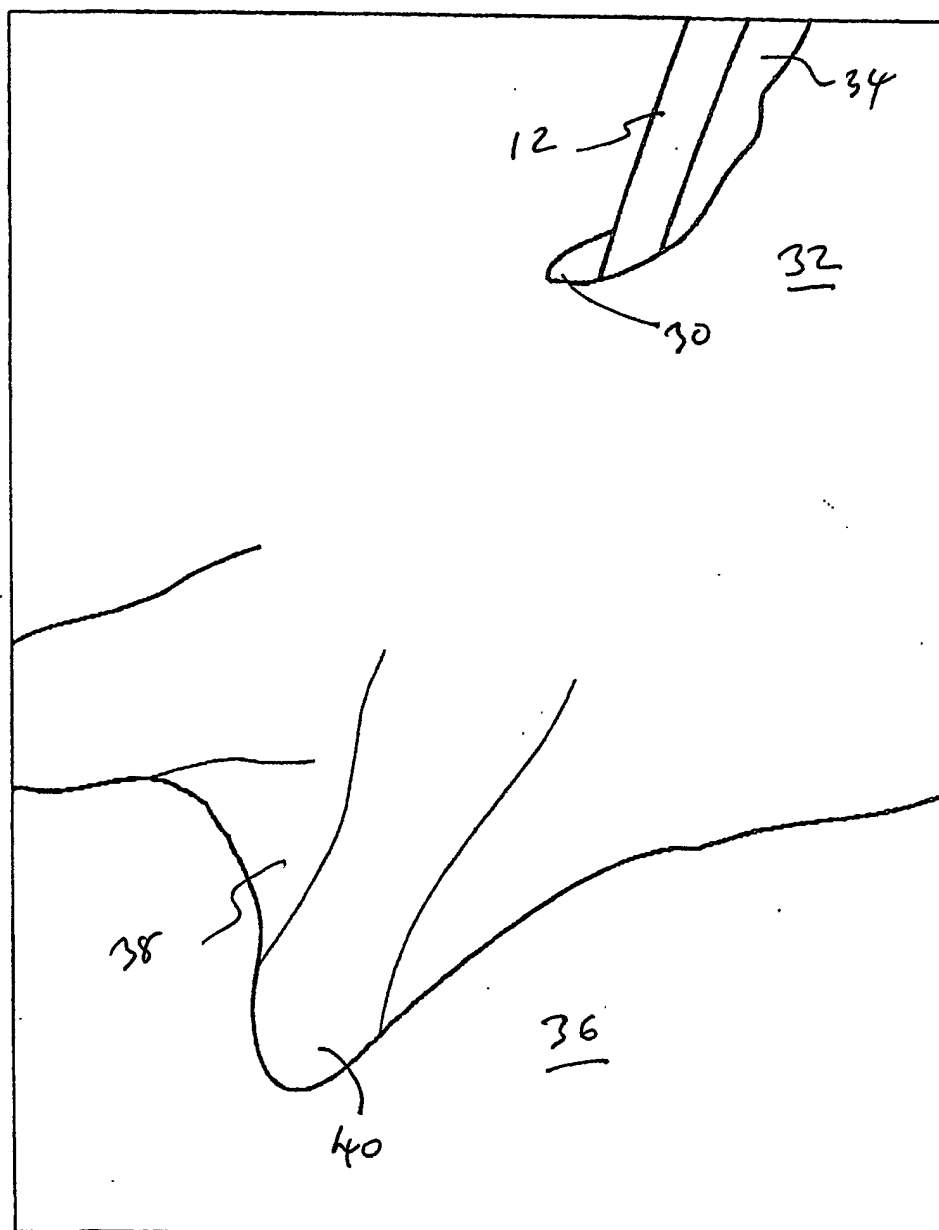


FIG 4

4/6

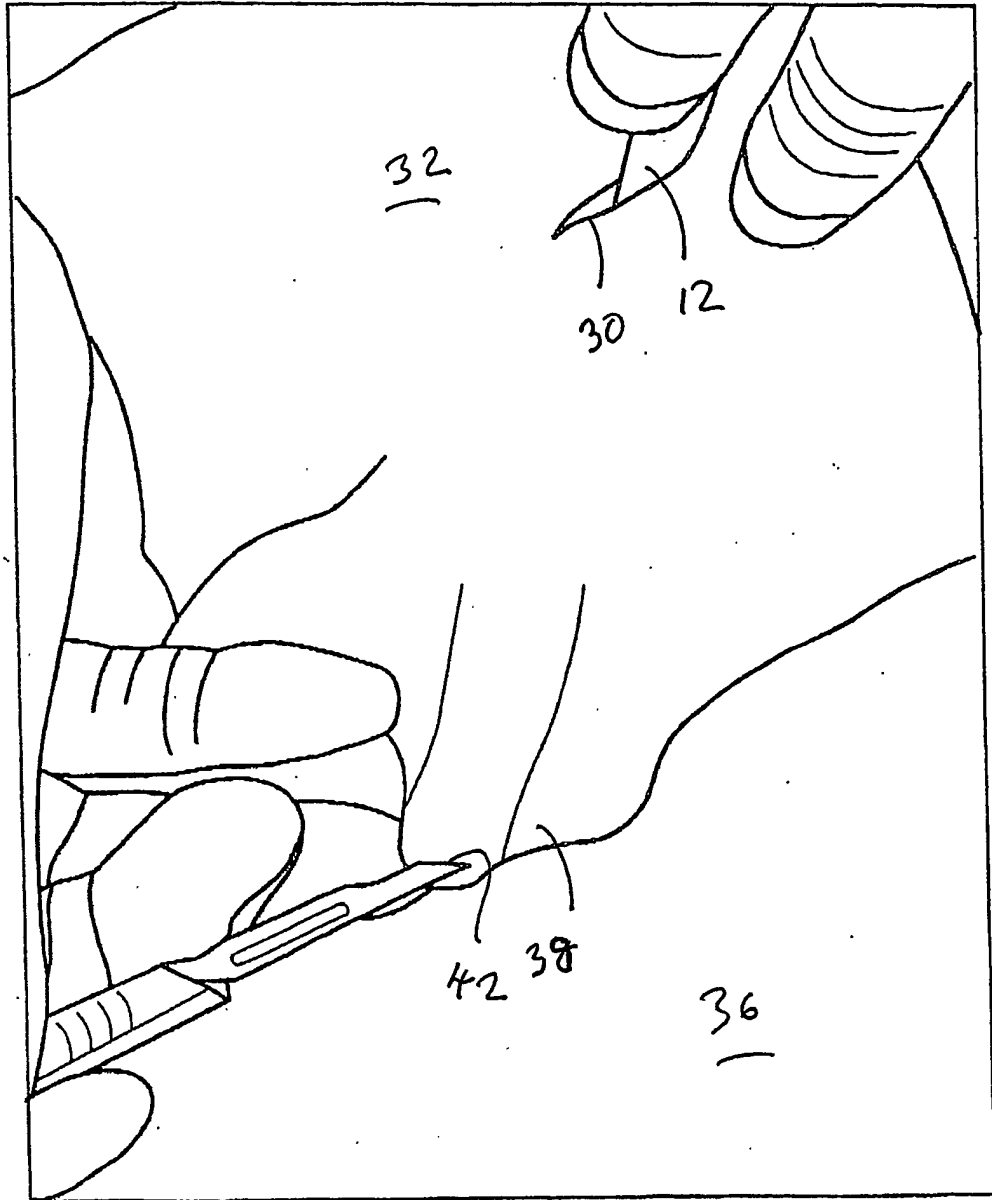


FIG 5

5/6

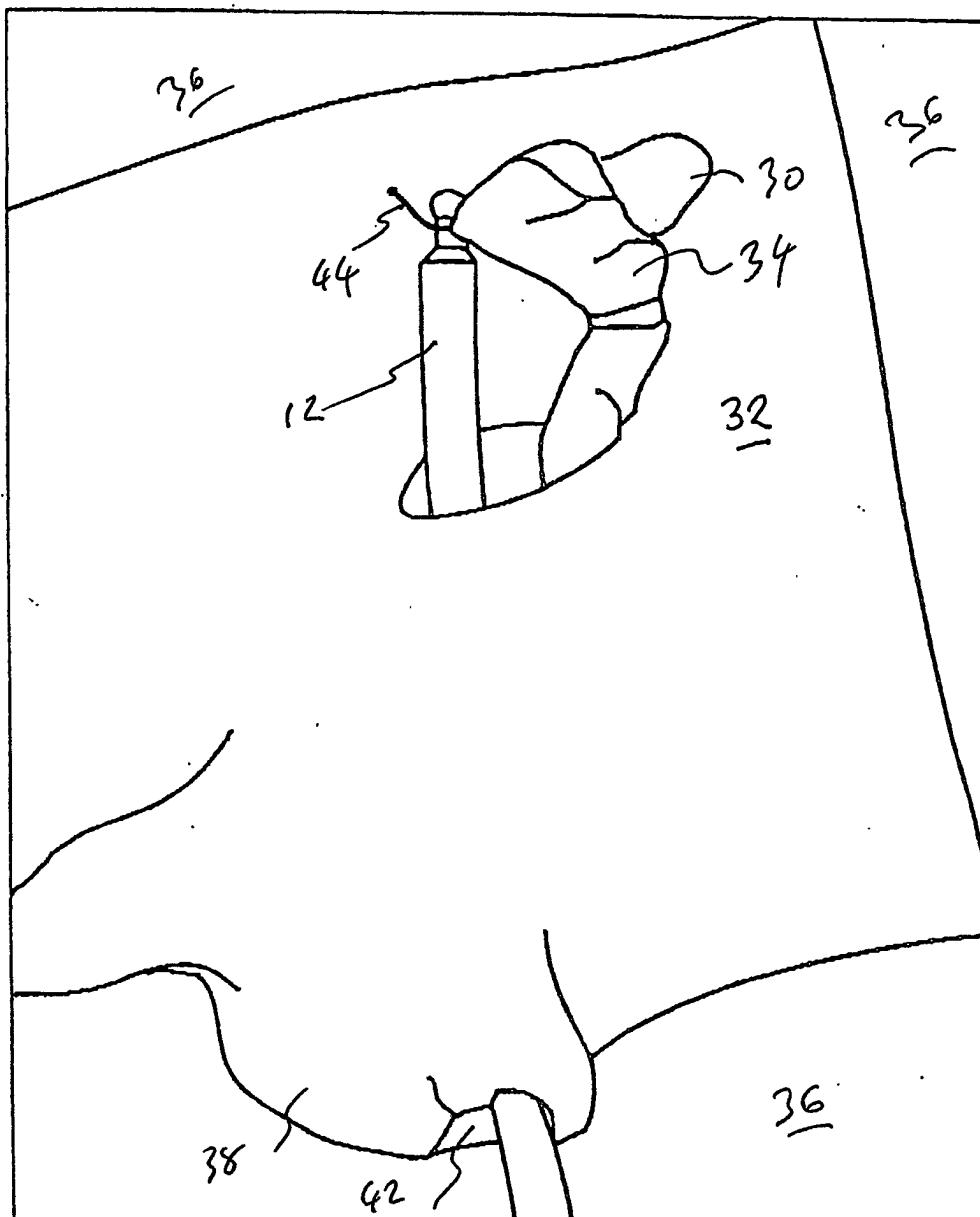


FIG 6

6/6

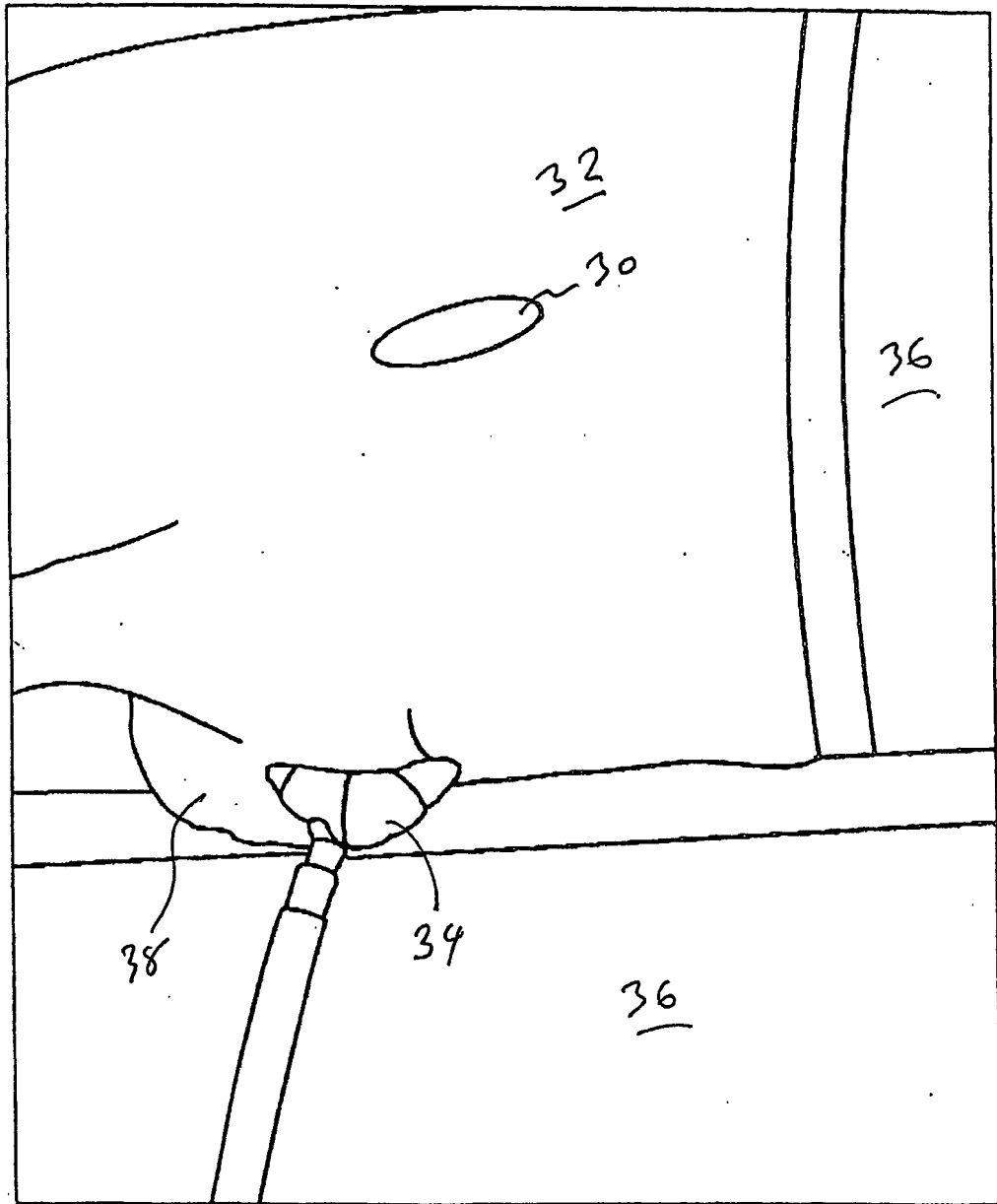


FIG 7.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.